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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,161

11/25/2003

B. Robert Franza JR.

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11/28/2006

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,161	<b>Applicant(s)</b> FRANZA ET AL.	
	<b>Examiner</b> Michele K. Joike, Ph.D.	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 22 is/are rejected.
- 7) ☒ Claim(s) 20-21 and 23-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed September 18, 2006. Claims 18-30 are pending and under consideration in the instant application.

Any rejection of record in the previous Office Action, mailed June 14, 2006, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,338,686 (hereinafter Hellerstein).

### ***Response to Arguments Concerning Claim Rejections – 35 USC § 102 (b)***

Applicants' arguments filed September 18, 2006 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Hellerstein teaches a method similar to that of Applicants, but instead of using a simple calculation of relative abundance, Hellerstein teaches the determination of the frequency of the mass isotopomer of the biopolymer. Applicants set forth the difficulties in their specification of the determination of frequency as taught by Hellerstein.

These arguments are not found persuasive for the following reasons.

Applicants' invention is a method for determining the rate of degradation of a biopolymer comprising adding a stable isotope-labeled monomer to a biopolymer pool, collecting first and second samples and measuring the relative abundance of monoisotopic and isotopomeric peaks, calculating the difference between the peaks of the first and second samples and determining the rate of polymer degradation.

Hellerstein teaches a method for determining the rate of degradation of an isotopically labeled biopolymer comprising adding a stable isotope-labeled subunit (monomer) to a biopolymer pool, collecting first and second samples and measuring the relative abundance of monoisotopic and isotopomeric peaks using mass spectrometry, calculating the difference between the peaks of the first and second samples and determining the rate of biopolymer decay. Serial timepoints were collected and individual mass isotopomers were plotted over time to determine the rate of decay. Therefore, Hellerstein teaches every element of the claimed invention.

Hellerstein uses mass spectrometry for his calculations which Applicants state, in their specification on page 2, is a problem. However, Applicants use mass spectrometry in their example, and specifically state on p. 13 of their specification that

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mass spectrometry can be used for the calculations. Applicants use open language in their claims and do not preclude the use of mass spectrometry. Hellerstein teaches every step of Applicants' invention and makes the same calculations; he just uses mass spectrometry to do them. Furthermore, Hellerstein also teaches (column 7, lines 1-6) that any calculation means which provides relative values for abundance of such isotopomers in a sample may be used in describing data.

***Allowable Subject Matter***

Claims 20-21 and 23-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER